

Notice of Allowability

Application No.

09/787,970

Examiner

Anne Holleran

Applicant(s)

LINDHOLFER ET AL.

Art Unit

1643

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to after-final amendment of 6/17/2005.
2. ☒ The allowed claim(s) is/are 1-39 (claim 39 added by examiner's amendment).
3. ☒ The drawings filed on 26 September 2001 are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____ |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____ |

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Chuan Gao on July 25, 2005.

The application has been amended as follows:

In the specification:

at page 11, lines 29-30, replace the phrase "if they exhibit the properties and effects characterized in Claim 1" with the phrase "having the following properties of: binding to a T cell; binding to at least one antigen on autologous tumor cells or allogeneic tumor cells; and binding via Fc portions (in the case of bispecific antibodies) or via a third specificity (in the case of trispecific antibodies) to Fc receptor-positive cells".

In the claims:

In claim 1, line 1, the word "a" was added after the word "against" and before the word "tumor".

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Claim 6. The method according to claim 5 wherein said antibodies [are able to] bind to monocytes, [makrophages] macrophages, dendritic cells, “natural killer” cells (NK cells) and/or activated neutrophils being Fc γ receptor I-positive cells.

Claim 7. The method according to claim 1 wherein said antibodies [are capable of inducing] induce tumor-reactive complement-binding antibodies[and therefore of inducing], thereby inducing a humoral immune response.

Claim 8. The method according to claim 1 wherein said antibodies [are selected to] bind to the T cells via CD2, CD3, CD4, CD5, CD6, CD8, CD28, [and/or] or CD44.

Claim 9. The method according to claim 1 wherein said antibodies, [are selected so that] following their binding to the Fc receptor-positive cells, initiate or increase the expression of co-stimulatory antigens CD40, CD80, CD86, ICAM-1 and /or LFA-3 [being co-stimulatory antigens] and/or initiate or increase the secretion of [cytokins] cytokines by the Fc receptor-positive [cell is initiated or increased] cells.

Claim 10. The method according to claim 9, wherein the antibodies [are selected so that the] increase the secretion of IL-1, IL-2, IL-4, IL-6, IL-8, IL-12, INF- γ [being cytokins] and/or TNF- α [is increased].

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Claim 16. The method according to claim 1 wherein the tumor cells have been treated by irradiation or by a chemical substance.

Claim 21. The method according to claim 20 wherein the surface antigens are present in an amount of at least 100 antigens and at the most 500,000 antigens per tumor cell.

Claim 22. The method according to claim 21 wherein the antibody [is capable of activating] activates Fc receptor-positive cells [whereby] thereby initiating or increasing the expression of [cytokins] cytokines and/or costimulatory antigens [is initiated or increased].

The following claim was added:

Claim 39. The method of claim 1, wherein the antibodies are administered in an amount of about 1-100 μg .

REASONS FOR ALLOWANCE

The following is an examiner's statement of reasons for allowance: The rejection of claims 1, 4-23 and 28-36 under 35 U.S.C. 103(a) is withdrawn in view of the amendment to claim 1, limiting the interval between administration of the inactivated tumor cells and the administration of the bispecific or trispecific antibodies to 1-48 hours.

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The provisional obviousness-type double-patenting rejection of claims 1-38 as being unpatentable over claims 1-24 of copending Application No. 10/378,218 is withdrawn because according to MPEP 822.01, if a provisional double patenting rejection is the only remaining rejection in the case following entry of an amendment, the examiner should withdraw the rejection and permit the application to issue as a patent. In this case, the amendment filed 6/17/2005 obviated all of the other rejections of record, and the only remaining rejection was the provisional double patenting rejection. Therefore, the double patenting rejection is withdrawn.

Support for claim 39 is found in the originally filed claim 4.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (571) 272-0833. Examiner Holleran can normally be reached Monday through Friday, 9:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached at (571) 272-0832.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 571-1600.

Anne L. Holleran
Patent Examiner
July 26, 2005

Alana M. Harris
ALANA M. HARRIS, PH.D.
PRIMARY EXAMINER
07/29/2005